MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**1427**	
Subject:	**Non-Invasive Prenatal Aneuploidy and Other Prenatal Genetic Testing**	
Section:	**Medical Non-Pharmacy Protocols**	
Initial Effective Date:	**12/03/2020**	
Revision Effective Date(s):	**07/21, 07/22**	
Review Effective Date(s):		
Responsible Parties:	**Patryce A. Toye, MD, Lisa Speight, MD**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**MDH Policy Non-Invasive Prenatal Testing (NIPTs) Clinical Criteria (12/20/20) and Non-Invasive Prenatal Testing (NIPTs) Ordering Guidelines**	
Approved:	**Theresa Bittle, RN** **AVP, Clinical Operations**	**Patryce A. Toye, MD** **Chief Medical Officer**

Purpose: **To define the conditions under which MedStar Family Choice (MFC) will provide Non-Invasive Prenatal Aneuploidy Testing and other prenatal genetic testing for screening.**

Scope: **MedStar Family Choice, Maryland**

Policy: **It is the policy of MFC to offer non-invasive prenatal screening testing without authorization for trisomy 13, 18 and 21 in accordance with MDH and ACOG recommendations. Testing beyond these screening tests will require prior authorization.**

Procedure:

Basic Screening:

1. Prenatal screening for fetal aneuploidy will be available for all pregnant women without prior authorization starting at 10 weeks gestational age for **singleton pregnancy only**.
2. First Trimester Screening should include an ultrasound and aneuploidy screening OR traditional Quad screening but NOT both. Ultrasound and NIPTs is the preferred method.
3. LabCorp and Myriad are MedStar Family Choice's contracted laboratories. OB GYN providers must send samples to one of these laboratories.
4. For LabCorp, the only test ordered should be "**MaterniT21 PLUS Core + SCA**". It is **LabCorp test #451934** and it will report aneuploidy for chromosome 21, 18 and 13, sex chromosome aneuploidy (Turner syndrome, Klinefelter syndrome, etc.) and sex of the

baby. If this **EXACT** test is ordered, no prior authorization will be required. Any other test will require prior authorization.

5. For Myriad, on their order form under *Myriad Prequel Prenatal Screen -Noninvasive prenatal screen*, check the box for *Common aneuploidy, chromosome 13, 18, 21* AND check the box next to *Include sex chromosome analysis*. If these two boxes are checked, no prior authorization will be required. Any other test will require prior authorization. (see Myriad Order Form inserted below)
6. Second Trimester Screening should still include a detailed anatomic ultrasound and an alfa fetal protein level.

Advanced Testing:

Further genetic testing will require prior authorization and must be ordered by a Maternal Fetal Medicine Specialist or after consultation with a Genetic Counselor and would most likely be a requested for abnormal anatomic findings on sonogram, a family history of DiGeorge syndrome, Cri Du Chat, prior rare trisomy, etc.

1. Requests must be submitted with evidence of consultation with a Maternal Fetal Medicine Specialist or a Genetic Counselor.
2. The medical records submitted must indicate the reason for the request, the condition suspected and the anticipated actions or change of clinical management to be taken based on the outcome of the testing.
3. For LabCorp, the specific testing requested would be **MaterniT21 Genome Add On (LabCorp test # 452104 or 452114** if redraw needed) which would return a "comprehensive chromosome copy number analysis including unbalanced derivatives, and information about deletions or duplications of chromosome material 7 Mb or larger, as well as analysis of seven clinically relevant microdeletions less than 7 Mb in size." Any other version of the LabCorp MaterniT21 tests would duplicate the original screening test and is thus not medically necessary.
4. For Myriad, on their order form check ONLY the box next to *microdeletions, singleton only* (see Myriad Order Form inserted below)
5. Any other genetic testing will require consultation with Maternal Fetal Medicine or Genetic Counselor and documentation as in 2. above.

Out of Network Testing:

1. All requests for out of network laboratories will require prior authorization and will only be approved if the testing is not available from an in-network laboratory and is determined to be medically necessary

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Per the MDH policy

CPT 81420 (Fetal chromosomal aneuploidy (e.g., trisomy **21**, monosomy X) genomic sequence analysis panel, circulating cell- free fetal DNA in maternal blood, must include analysis of chromosomes **13**, **18**, and **21**) - no PA for Prenatal testing
CPT 81507 (Fetal aneuploidy (trisomy **21**, **18**, and **13**) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy) - no PA for Prenatal testing
CPT 81422 (Fetal chromosomal microdeletion(s) genomic sequence analysis (e.g., DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood) - PA required
CPT 81479 (Unlisted molecular pathology procedure)– PA required (this CPT may only be used for NIPTs testing)

References: Content created in conjunction with MSH OBGYN Clinical Practice Council.

Attachments:
Attachment A – Myriad Order Form

Summary of Changes:	**07/22:** • Added Attachment A - Myriad Order Form. **07/21:** • Updated Responsible Departments from Utilization Management to Clinical Operations. **12/20:** • New policy.

Attachment A

FORESIGHT | PREQUEL

REQUISITION FORM

for Foresight Carrier Screen and Prequel Prenatal Screen

1. At a minimum, the patient's name, DOB and address must be included on this requisition (even if the patient's name is included elsewhere). Not doing so will result in sample delays.

2. Please note that if more than one ethnicity is selected, race will be reported as Other/ Mixed Caucasian, unless Ashkenazi Jewish has been selected. If no ethnicity is selected, Northern European will be reported.

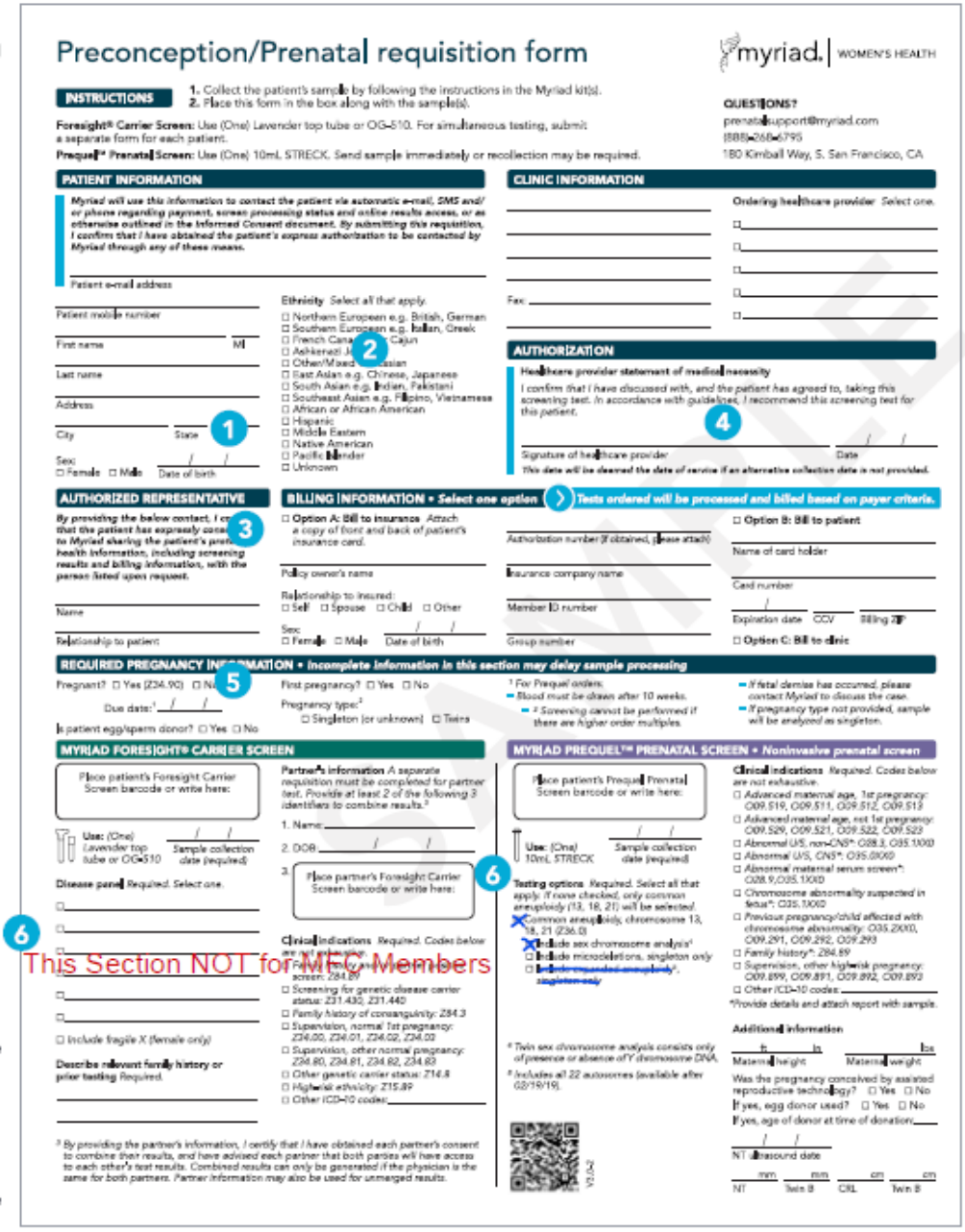
3. If selecting this option, please ensure that the insurance carrier information is filled out, even if a copy of the insurance card is included. Please do not fill out this information if the patient is selecting Option B or C.

4. Please make sure to date and sign this form.

5. Indicate whether the patient is pregnant at the time of testing.

6. Please fill this in. Clinical information is necessary and missing information can result in sample delays. If marking a code with an asterisk, please provide more information (reports, clinical data, etc.).

- Some insurers may require additional paperwork. Please contact your clinic's account executive for information on relevant forms or with any questions.
- When merging orders for a couple: 1) A separate requisition form must be filled out in its entirety for the partner, 2) The ordering clinician must be the same for both patients, 3) Results will not be released until both partners results have been completed.



Preconception/Prenatal requisition form

myriad. WOMEN'S HEALTH

INSTRUCTIONS
1. Collect the patient's sample by following the instructions in the Myriad kit(s).
2. Place this form in the box along with the sample(s).

Foresight® Carrier Screen: Use (One) Lavender top tube or OG-510. For simultaneous testing, submit a separate form for each patient.
Prequel™ Prenatal Screen: Use (One) 10mL STRECK. Send sample immediately or recollection may be required.

QUESTIONS?
prenatalsupport@myriad.com
(888)-268-6795
180 Kimball Way, S. San Francisco, CA

PATIENT INFORMATION
CLINIC INFORMATION
AUTHORIZATION
AUTHORIZED REPRESENTATIVE
BILLING INFORMATION • Select one option
REQUIRED PREGNANCY INFORMATION • Incomplete information in this section may delay sample processing
MYRIAD FORESIGHT® CARRIER SCREEN
MYRIAD PREQUEL™ PRENATAL SCREEN • Noninvasive prenatal screen

- When ordering both Prequel and Foresight for a couple, please note that **three** samples and **two** test requisitions are required. Send in two separate samples for the female patient (saliva or 4ml blood and 10ml blood) and **one** requisition and **one** sample for her partner (saliva or 4ml blood). For ease of use, all samples can be sent in one FedEx envelope.